

WE CLAIM:

1 1. A method for the identification of a systemic autoimmune disease
2 in a test subject suspected of suffering from an otherwise unidentified systemic
3 autoimmune disease selected from the group consisting of systemic lupus erythmatosus,
4 scleroderma, Sjögren's syndrome, polymyositis, dermatomyositis, CREST, and mixed
5 connective tissue disease, said method comprising:

6 (a) analyzing a single biological sample from said test subject for the
7 presence and amounts of a plurality of autoantibodies to produce a test data set;

8 (b) comparing said test data set to a library of reference data sets, each
9 reference data set obtained from a biological sample of a reference subject known
10 to have a systemic autoimmune disease of known identity; and

11 (c) applying pattern recognition means to produce a statistically derived
12 decision indicating which systemic autoimmune disease said test subject is
13 suffering from.

1 2. A method in accordance with claim 1 in which said test subject is
2 suffering from two systemic autoimmune diseases, and step (c) comprises applying
3 pattern recognition means to produce a statistically derived decision indicating which two
4 systemic autoimmune diseases said test subject is suffering from.

1 3. A method in accordance with claim 1 in which said pattern
2 recognition means is a member selected from the group consisting of k-nearest neighbor
3 analysis, multi-linear regression analysis, Bayesian probabilistic reasoning, neural
4 network analysis, and principal component analysis.

1 4. A method in accordance with claim 1 in which said pattern
2 recognition means is a k-nearest neighbor analysis.

1 5. A method in accordance with claim 1 in which said plurality of
2 autoantibodies numbers from 10 to 100 autoantibodies.

1 6. A method in accordance with claim 1 in which said plurality of
2 autoantibodies numbers from 15 to 25 autoantibodies.

1 7. A method in accordance with claim 1 in which said plurality of
2 autoantibodies comprises antibodies to at least fifteen of the following antigens:

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3	SSA 60
4	SSA 60
5	SSA 52
6	SSB 48
7	Sm BB'
8	Sm D1
9	RNP 68
10	RNP A
11	RNP C
12	Fibrillarin
13	Riboproteins P0, P1, and P2
14	dsDNA
15	Nucleosome
16	Ku
17	Centromere A
18	Centromere B
19	Scl-70
20	Pm-Scl
21	RNA-Polymerases 1, 2, and 3
22	Th
23	Jo-1
24	Mi-2
25	PL7
26	PL12
27	SRP

1 **8.** A method in accordance with claim 1 in which said plurality of
2 autoantibodies comprises antibodies to each of the following antigens:

3	SSA 60
4	SSA 60
5	SSA 52
6	SSB 48
7	Sm BB'
8	Sm D1

9 RNP 68
 10 RNP A
 11 RNP C
 12 Fibrillarin
 13 Riboproteins P0, P1, and P2
 14 dsDNA
 15 Nucleosome
 16 Ku
 17 Centromere A
 18 Centromere B
 19 Scl-70
 20 Pm-Scl
 21 RNA-Polymerases 1, 2, and 3
 22 Th
 23 Jo-1
 24 Mi-2
 25 PL7
 26 PL12
 27 SRP

1 9. A method in accordance with claim 1 in which said library of
 2 reference data sets represents from 100 to 10,000 biological samples from reference
 3 subjects known to have systemic autoimmune diseases of known identity.

1 10. A method in accordance with claim 1 in which said library of
 2 reference data sets represents from 200 to 2000 biological samples from reference
 3 subjects known to have systemic autoimmune diseases of known identity.

1 11. A method in accordance with claim 1 in which step (c) further
 2 comprises assigning a confidence level to said determination.

1 12. A method in accordance with claim 1 in which said biological
 2 sample from said test subject is a member selected from the group consisting of serum,
 3 plasma, urine, and cerebrospinal fluid.

1 **13.** A method in accordance with claim 1 in which said biological
2 sample from said test subject is serum.

1 **14.** A method in accordance with claim 1 in which step (a) is
2 performed by immunoassay.

1 **15.** A method in accordance with claim 1 in which step (a) is
2 performed by immunoassay with fluorescence detection.

1 **16.** A method in accordance with claim 1 in which said systemic
2 autoimmune disease is systemic lupus erythematosus.

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